DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 2, 2015

Medacta USA
Mr. Adam Gross
Director of Regulatory, Quality and Compliance
1556 West Carroll Avenue
Chicago, Illinois 60607

Re: K143453
Trade/Device Name: Mpact Double Mobility System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, MEH
Dated: December 22, 2014
Received: December 30, 2014

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143453

Device Name
Mpact Double Mobility System

Indications for Use *(Describe)*
The hip prosthesis is designed for cementless use in total hip arthroplasty in primary or revision surgery. The patient should be skeletally mature.
The patient's condition should be due to one or more of:
• Severely painful and/or disabled joint: as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis or psoriactic arthritis, congenital hip dysplasia, ankylosing spondylitis.
• Avascular necrosis of the femoral head.
• Acute traumatic fracture of the femoral head or neck.
• Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement where sufficient bone stock is present.
• Dislocation risks

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Applicant/Sponsor: Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

Contact Person: Adam Gross
Director of Regulatory, Quality and Compliance
Medacta USA
1556 W Carroll Ave
Chicago, IL 60607
Phone: (805) 910-6511
Fax: (805) 437-7553
Email: AGross@medacta.us.com

Date Prepared: November 19, 2014

DEVICE INFORMATION

Trade/Proprietary Name: Mpact Double Mobility System
Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Class II
21 CFR 888.3358, Product Code LPH
21 CFR 888.3353, Product Code LZO, MEH

Predicate Device(s):

510(k)	Product	510(k) Holder	Clearance Date
K083116	Versafitcup Double Mobility	Medacta International	4/7/2009
K092265	Versafitcup DM Highly Crosslinked	Medacta International	3/12/2010
K103721	Mpact Acetabular System	Medacta International	3/21/2011
K132879	Mpact Extension	Medacta International	1/22/2014
K131458	Mpact DM Converter	Medacta International	10/1/2013

Product Description

The Mpact Double Mobility System acetabular shells are designed to be used with the Medacta Total Hip Prosthesis System. The Mpact Double Mobility System consists of acetabular shells (size 42mm to 66mm in 2mm increments) that have a TiGrowth porous coating (Ti, ASTM F1580) and hemispherical shape that is identical to the K103721 and K132879 predicate devices. The material of the shells (High Nitrogen StSt – ISO 5832-9) and the double mobility design is the same as the K083116 predicate device.

The shells are used with the Versafitcup Double Mobility Liners that are registered with K083116, K092265, and K131458 predicate devices in addition to one new size (*22.2/DMA*) of the Medacta Double Mobility liner in both UHMWPE (ISO 5834-2 Type 1) and HighCross highly crosslinked UHMWPE which are included in this submission. These liners are identical to the liners in the K083116, K092265, and K131458 submissions but have a smaller external diameter than the predicates. These new liners can only be coupled with a 22.2mm femoral head and have a minimum thickness of 5 mm.

Indications for Use

The hip prosthesis is designed for cementless use in total hip arthroplasty in primary or revision surgery. The patient should be skeletally mature.
The patient's condition should be due to one or more of:
• Severely painful and/or disabled joint: as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis or psoriactic arthritis, congenital hip dysplasia, ankylosing spondylitis.
• Avascular necrosis of the femoral head.
• Acute traumatic fracture of the femoral head or neck.
• Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement where sufficient bone stock is present.
• Dislocation risks

Comparison to Predicate Devices

The indications for use, design features and materials of the Mpact Double Mobility System are substantially equivalent to those of the predicate devices. The substantial equivalence of the Mpact Double Mobility System implants is supported by the performance testing, materials information, and data analysis provided within this Premarket Notification.

Performance Testing

The Mpact Double Mobility System was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system. The Mpact Double Mobility System was compared to the worst case predicate device and it was determined that the Mpact Double Mobility System is not worst case.

Mpact Double Mobility System has similar performance testing as the predicates in terms of:

Acetabular shell:

- Coating adhesion and chemical characterization
- Friction test - ASTM G115-04 and ASTM D4518-94
- Ion release and corrosion test - ASTM F746-04

Acetabular shell and liner:

- Excessive wear during motion
- Limited ROM
- Dislocation Risk

Acetabular liner:

- Instability risk of the modular connection of the Mpact Double Mobility Liner and femoral head

Conclusion:

Based on the above information, the Mpact Double Mobility System can be considered as substantially equivalent to its predicate devices.